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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,754	07/23/2003	Steven M. Leventer	JAN-027 CON	8132

7590 05/17/2005

Vela Pharmaceuticals
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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/625,754	**Applicant(s)** LEVENTER ET AL.	
	Examiner Raymond J. Henley III	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): the objection to the specification and rejection of claims 1-5..
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *29-31*.
   Claim(s) objected to: *32-35*.
   Claim(s) rejected: *28*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see "Attachment to Advisory Action"..
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Raymond J Henley III
Primary Examiner
Art Unit: 1614

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ATTACHMENT TO ADVISORY ACTION

Applicants' amendments filed April 20, 2005 and May 6, 2005 (a formal version of the April 20, 2005 amendment) have been received and entered. Accordingly, the specification at page 1 and claims 28-32 have been amended, claims 1-5 have been canceled and claims 33-35 have been added.

In light of the amendments, the objection to the specification and, because of the cancellation of claims 1-5, the rejection of claims 1-5 under 35 U.S.C. § 102(a) as set forth in the previous Office action dated March 29, 2005 are withdrawn.

Informalities Noted

Claim 32 is objected to as being incomplete for not including the therapeutic objective to be accomplished by the administration, i.e., treating convulsions, or a host in whom or to whom the composition is administered. The claim should be amended appropriately.

Allowable Subject Matter

Claims 29 and 33 require, as a lower limit, an S-tofisopam amount of 10 mg. Landry et al. (U.S. Patent No. 6,080,736), disclose a composition containing S-tofisopam, DMSO, distilled water and Tween 80 (Table 1, col. 21). The dosage of S-tofisopam in the composition is reported to be "30 mg/kg". The actual amount in the composition cannot be determined because the weight of the rat(s) to which it was administered is not reported. Also, because S-tofisopam is not an active agent of the reference, i.e., it was administered only to show results comparative to the R-isomer and showed no activity under the conditions tested, one of ordinary skill in the art would have had no motivation to modify this composition in any manner.

The claims are believed to distinguish over Landry et al. because, as set forth in the previous Office action dated August 16, 2004 at page 3, last full paragraph, an average rat weight of from 250 to 300 grams is the best "factual" determination possible, under the current circumstances. Thus, Landry is taken to teach an S-tofisopam amount of from 30mg/kg x (250 to 300 grams) or a range of from 7.5 to 9 mg which is outside of the range required by claims 29 and 33.

Claims 30 and 31 require S-tofisopam amounts which are greater than 10 mg and thus are also distinguished from Landry et al.

The dosage of claim 32, i.e., less than 30 mg/kg, is not taught or suggested by Landry because one of ordinary skill in the art would not have been motivated to modify the dosage of S-tofisopam administered in Landry et al..

Claims 33-35 are directed to compositions and require S-tofisopam amounts consistent with those amounts of claims 29-31. Claims 33-35, however, depend from claim 28 which remains rejected for the reasons below. Therefore, claims 33-35 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

Claim 28 Remains Rejected

Claim 28 remains properly rejected because the statement of intended use in the claim, i.e., "wherein the composition is for intraperitoneal, subcutaneous, intranasal, intramuscular, intrathecal, sublingual, rectal, intravenous infusion, or transdermal delivery", does not impart any physical characteristic to the claimed composition that is not present in the composition of Landry et al. which contains S-tofisopam, DMSO, distilled water and Tween 80 (Table 1, col. 21). Because claim 28 is directed to a composition and not a method, the fact that Landry may

teach the composition for oral consumption is not distinguishing. The composition of this claim is evaluated against the composition of Landry et al. in terms of what it is and not how it is used.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 12, 2005